

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

In re: Seroquel XR (Extended Release
Quetiapine Fumarate) Antitrust Litig.

Master Dkt. No. 20-1076-CFC

This Document Relates To:
All Actions

**PLAINTIFFS' MOTION PURSUANT TO FEDERAL RULE OF CIVIL
PROCEDURE 59(E) AND LOCAL CIVIL RULE 7.1.5 FOR
RECONSIDERATION OR REARGUMENT REGARDING
THE COURT'S FEBRUARY 9, 2023 ORDER
DENYING PLAINTIFFS' MOTION TO COMPEL**

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I. INTRODUCTION

Pursuant to Fed. R. Civ. P. 59(e) and Local Rule 7.1.5, Plaintiffs move for reconsideration or reargument of their motion to compel production of the settlement agreements AstraZeneca (“AZ”) entered with Abbreviated New Drug Application (“ANDA”) filers other than Handa (the “non-Handa Generics”) (ECF No. 259-2 ¶3). These agreements are relevant to when the non-Handa Generics could enter the market absent the challenged reverse payment by AZ to Handa. The Court’s ruling denying Plaintiffs’ motion to compel production of these agreements is premised on two clear errors of law. *First*, at least some of the non-Handa Generics entered consent judgments that appear to permit entry before November 1, 2016 if such earlier entry is “specifically authorized pursuant to the Settlement Agreement.”¹ As a matter of law, the fact that the consent judgments incorporate the settlement agreements by reference makes the agreements relevant.

Second, the Court’s denial of Plaintiffs’ motion was based on an erroneous

¹ Consent J., *AstraZeneca Pharms. LP v. Accord Healthcare, Inc.*, No. 3:08-cv-4804 (D.N.J.), ECF No. 206 (Oct. 07, 2011); Consent J., *AstraZeneca Pharms. LP v. Intellipharms. Corp.*, No. 1:11-cv-4498 (S.D.N.Y.), ECF No. 36 (July 30, 2012); Consent J., *AstraZeneca Pharms. LP v. Amneal Pharms. LLC*, No. 3:12-cv-4841 (D.N.J.), ECF No. 19 (Jan. 16, 2013); Consent J., *AstraZeneca Pharms. LP v. Torrent Pharma Inc.*, 3:10-cv-4205 (D.N.J.), ECF No. 162 (Feb. 8, 2013); Consent J., *AstraZeneca Pharms. LP v. Lupin Ltd.*, No. 3:12-cv-6888 (D.N.J.), ECF No. 18 (Apr. 11, 2013); Consent J., *AstraZeneca Pharms. LP v. Pharmadax USA, Inc.*, No. 1:14-cv-6557 (D.N.J.), ECF No. 27 (Feb. 19, 2015) (similar); Consent J., *AstraZeneca Pharms. LP v. Macleods Pharms., Ltd.*, No. 2:15-cv-1513 (D.N.J.), ECF No. 10 (June 29, 2015) (similar).

assumption that the non-Handa Generics would be able to *automatically* enter 180 days after Handa's launch of generic Seroquel XR pursuant to the Hatch-Waxman Act. While the expiration of that exclusivity period was necessary for non-Handa Generics to enter, it was not sufficient. The "unless specifically authorized pursuant to the Settlement Agreement" language in the consent judgments confirms that the settlement agreements are relevant to fairly assess and rebut any AZ argument that the consent judgments barred the non-Handa Generics' entry until November 1, 2016, even if Handa entered months or years earlier. Notably, counsel for AZ *agreed* with Plaintiffs that Handa's earlier entry would *not* automatically accelerate the non-Handa Generics' entry. *See* Hr'g Tr. at 23:14-18.

The Court's ruling deprives Plaintiffs of discovery relevant to both causation and damages. In addition to showing that AZ made an unlawful reverse payment in exchange for Handa's agreement to delay its launch of generic Seroquel XR (the "violation" element of Plaintiffs' antitrust claim), Plaintiffs will prove that in the "But-For World" absent the illegal payment, Handa would have entered the market earlier. For example, to establish Handa's entry date absent the reverse payment, Plaintiffs may rely on a benchmark based on an alternative earlier settlement date that Plaintiffs' experts will show would have been profitable to both AZ and Handa as compared to continuing the litigation. If Handa entered earlier, Plaintiffs further expect to be able to show that other generic manufacturers would have also

launched earlier than they actually launched—but still after Handa—creating a second wave of generic competition. As a result, the non-Handa Generics’ settlement agreements are relevant to a causation analysis determining whether and when they would have launched following Handa’s launch, and to rebut arguments that absent terms in those agreements accelerating their entry, the non-Handa Generics “would have remained sidelined by contract.” *Zetia Antitrust Litig.*, 2022 WL 4362166, at *15 (E.D. Va. Aug. 15, 2022). Additionally, the number of subsequent generics that would enter is significant to assessing the amount of damages because each incremental additional generic on the market drives prices lower. Hr’g Tr. at 29:9-19, 75:3-8.

Contrary to the Court’s assumption, these causation and damages issues cannot be resolved as a matter of law, but are factual issues requiring discovery. If Defendants were willing to stipulate that the non-Handa Generics would enter 180 days following Handa (or sooner in the event of Handa’s forfeiture of its 180-day exclusivity), as the Court assumed, Plaintiffs would accept that stipulation. But because Defendants take the opposite position, the settlement agreements are important to determine when the non-Handa Generics could have entered. Because the prior ruling contains clear errors and would cause manifest injustice, the Court should reverse its decision and order production of the settlement agreements, or, in the alternative, grant reargument.

II. STANDARD

Reconsideration under FRCP 59(e) or reargument under Local Rule 7.1.5 is proper “to correct a clear error of law or fact or to prevent manifest injustice.”² “Reargument may be appropriate where the Court has patently misunderstood a party” or “has made an error not of reasoning but of apprehension.”³ “The court should reconsider its decision when the court has overlooked facts or precedent which, had they been considered, might reasonably have altered the result.”⁴

III. ARGUMENT

There is no dispute that the non-Handa Generics’ consent judgments enjoin them from marketing generic Seroquel XR “until November 1, 2016 . . . unless specifically authorized pursuant to the Settlement Agreement.” *Supra* at 1, n.1. “[C]onsent judgments should be interpreted in a way that gives effect to . . . [the parties’ intent] as reflected in the judgment itself or in documents incorporated in

² *Kelly v. Swartz*, 2021 WL 7209530, at *1 (D. Del. Dec. 22, 2021) [Connolly, J.] (citing *Lazaridis v. Wehmer*, 591 F.3d 666, 669 (3d Cir. 2010)).

³ *Id.* at *3.

⁴ *Middletown Concrete Prods., Inc. v. Black Clawson Co.*, 1992 U.S. Dist. LEXIS 18052, at *6 (D. Del. Nov. 18, 1992) (citation omitted); *see also Genentech, Inc. v. Amgen Inc.*, 2019 WL 4058929, at *2 (D. Del. Aug. 28, 2019) [Connolly, J.] (“At the time the motions for reargument were filed, I recognized that I may have improvidently issued my rulings[.]”); *Teri Woods Publ’g, L.L.C. v. Williams*, 2013 WL 6388560, at *2 (E.D. Pa. Dec. 6, 2013) (clear error is one that is “indisputable”); *In re Energy Future Holdings Corp.*, 904 F.3d 298, 312 (3d Cir. 2018) (“[A] direct, obvious, or observable error” causes manifest injustice if it is of “some importance to the larger proceedings”).

it by reference.” *Sovereign Bank v. REMI Capital, Inc.*, 49 F.4th 360, 367-68 (3d Cir. 2022) (citation omitted) (emphasis added). That alone justifies production of the settlement agreements—an argument that Plaintiffs presented, but which the Court overlooked. Hr’g Tr. at 7:14-18.

Plaintiffs are entitled to understand when and how entry of the non-Handa Generics would be accelerated or changed, if Handa had launched earlier in lieu of accepting a payment for delay. The Court properly recognized that Handa’s launch affects the non-Handa Generics. Hr’g Tr. at 27:21-23 (agreeing that Handa agreement “has cascading effects that apply to other generics”). But the Court incorrectly assumed that Handa’s earlier entry would automatically accelerate other generics. Hr’g Tr. at 17:18-21 (“Isn’t that a given? Under the law, that’s exactly what happens . . . of course, Accord’s entry [as a later-filer] is accelerated if Handa’s entry is accelerated.”). Respectfully, this was an error of apprehension.

While an earlier launch by Handa *could* accelerate launch by later generics by triggering Handa’s exclusivity period under Hatch-Waxman, it does not *automatically* entitle later generics to launch; entry of the non-Handa Generics is not a “legal question” based solely on Handa’s 180-day exclusivity. Hr’g Tr. at 11:21-22.⁵ Rather, “assessing whether another firm could have successfully

⁵ Plaintiffs’ counsel did not concede otherwise. Counsel’s response that the Court was “right” when it asked whether “as a matter of law” the later filers would “be allowed to” enter 180 days after Handa’s earlier entry referred only to the 180-day regulatory barrier. Counsel clarified a moment later that the non-Handa Generics’

brought [a competing drug] to market is . . . [a] fact-intensive inquiry.”⁶ Notably, at the February 9 hearing, AZ *agreed* with Plaintiffs that earlier entry by Handa would *not* have automatically accelerated entry by the non-Handa Generics on its own. Hr’g Tr. at 23:14-18. AZ may also argue that the consent judgments barred entry by non-Handa Generics until the dates in those judgments. But if the consent judgments permit earlier entry by the non-Handa generics under circumstances “specifically authorized” by the settlement agreements, Plaintiffs should be entitled to discover those circumstances.

Those circumstances likely appear in terms known as “contingent launch provisions,” also known as acceleration clauses, which “link[] the [generics] together for the purpose of entry dates.” *King Drug Co. of Florence v. Cephalon, Inc.*, 2014 WL 2813312, at *8 (E.D. Pa. June 23, 2014).⁷ The recent decision in *Zetia* is instructive. 2022 WL 4362166, at *15. There, plaintiffs’ expert opined that if the first-filer had entered earlier, two later filers—which had also settled with the

entering 180 days after an earlier Handa entry also “hinges, in part, on the terms of the . . . agreement[s].” Hr’g Tr. at 20:24-21:11.

⁶ *United Ass’n of Plumbers & Pipefitters Local 322 of S. N.J. v. Mallinckrodt ARD, LLC*, 2020 WL 5627149, at *16 (D.N.J. Aug. 18, 2020) (citing *Brader v. Allegheny General Hosp.*, 64 F.3d 869, 876 (3d Cir. 1995)).

⁷ See *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 245–46 (3d Cir. 2016) (“[T]he ‘contingent launch provision’ . . . allowed [one generic] to enter the . . . market if any other company entered. . . .”); *Fed. Trade Comm’n v. AbbVie Inc.*, 976 F.3d 327, 345 (3d Cir. 2020) (“Teva’s settlement triggered the acceleration clause in Perrigo’s settlement agreement, so Perrigo’s licensed entry date [moved up]”).

brand, in agreements not alleged to be unlawful—would also have launched earlier, because the later filers’ agreements contained acceleration clauses. *Id.* Those provisions were key because, irrespective of the expiry of the first filer’s 180-day exclusivity, “[w]ithout acceleration clauses,” the later-filer generics “*would have remained sidelined by contract until the expiry of . . . [the] patent.*” *Id.* at *15 (emphasis added). The court found the expert’s opinion reliable. *Id.* at *15-18.

Here, Plaintiffs will prove that, if AZ had not illegally induced Handa to delay its entry until November 1, 2016 with a reverse payment (its promise to not compete), as it did in the real world, Handa would have entered earlier in the But-For World.⁸ Further, Plaintiffs will show that if Handa had entered the market earlier, other generics would have entered earlier as well (though still after Handa).⁹ The non-Handa Generics’ entry dates will correspondingly be highly relevant to the amount of damages caused by AZ’s reverse payment, since each incremental generic on the market drives prices lower.¹⁰

⁸ Courts routinely recognize an “alternative settlement theory of causation” to establish an earlier generic entry date absent a reverse payment. *See, e.g., In re Androgel Antitrust Litig. (No. II)*, 2018 WL 2984873, at *16-17 (N.D. Ga. June 14, 2018) (collecting cases). The permissibility of any expert opinions Plaintiffs may or may not offer to support such a theory is not before the Court.

⁹ Plaintiffs do not contend that any settlement provision would have “allowed for [a non-Handa Generic] to enter *before* Handa,” as the Court suggested. Hr’g Tr. at 33:10-12 (emphasis added).

¹⁰ It is not correct, as the Court stated, that Plaintiffs “didn’t make a damages

There are multiple indications that one or more of the non-Handa Generics' settlement agreements contain acceleration clauses. As noted above, the consent judgments provide that the non-Handa Generics may enter earlier than November 1, 2016 if "specifically authorized pursuant to the Settlement Agreement[s]," implying that terms in those agreements accelerate generic entry. Other documents similarly describe settlements with non-Handa Generics as granting a license to enter on November 1, 2016 or "earlier upon certain circumstances."¹¹ Plus, the one agreement AZ *has* produced—the Handa agreement—contains an acceleration clause, defining Handa's "Entry Date" as "the earliest of (a) November 1, 2016; [or] . . . the date prior to November 1, 2016 on which any Third Party launches a Generic Quetiapine Fumarate product or Authorized Generic . . . under a license or other agreement with AstraZeneca." MTC Ex. 2 ¶ 5.2(c).¹² Just as Handa's agreement contains

claim." Hr'g Tr. at 42:7-11. Plaintiffs repeatedly argued that the agreements are relevant to damages. *See id.* at 29:9-19, 75:3-8.

¹¹ *See, e.g.*, "AstraZeneca enters into a settlement agreement with Handa Pharmaceuticals," Sept. 29, 2011, <https://www.astrazeneca.com/media-centre/press-releases/2011/AstraZeneca-enters-into-a-settlement-agreement-with-Handa-Pharmaceuticals-regarding-US-SEROQUEL-XR-patent-litigation-29092011.html#> (emphasis added); "AstraZeneca enters into a settlement agreement with Accord Healthcare, Inc.," Oct. 5, 2011, <https://www.astrazeneca.com/media-centre/press-releases/2011/AstraZeneca-enters-into-a-settlement-agreement-with-Accord-Healthcare-Inc-and-Intas-Pharmaceuticals-Ltd-regarding-US-SEROQUEL-XR-patent-litigation-05102011.html#>; Ex. 1 at '618 (similar re: Pharmadax), at '620 (similar re: Macleods).

¹² The agreement also contains clauses accelerating Handa's entry based on other contingencies, such as AZ losing patent litigation. *Id.* ¶ 5.2(b)(ii, iii).

acceleration clauses defining the “certain circumstances” under which *Handa* was permitted earlier entry, the non-Handa Generics’ settlements likely contain acceleration clauses accelerating *their* entry to 180 days after *Handa*’s entry, in the event *Handa*’s entry were earlier in the But-For World.

The Court erred in holding that the simple fact of AZ executing the non-Handa Generic settlements *after* its settlement with *Handa* renders the agreements irrelevant. Hr’g Tr. at 75:9-15. While the Court correctly recognized that only events preceding the *Handa* Settlement are relevant to assessing the *violation* element of Plaintiffs’ antitrust claim, Plaintiffs are not seeking the non-Handa Generics’ settlement agreements to show that Defendants violated the Sherman Act. This discovery is relevant to causation and damages, and “nothing in the . . . case law suggests that the strict ex ante lens . . . must also apply to the question of causation.” *Apotex, Inc. v. Cephalon, Inc.*, 255 F. Supp. 3d 604, 614 (E.D. Pa. 2017)). Even AZ has not taken the position in the meet-and-confer process that discovery postdating the *Handa* settlement is irrelevant to causation and damages.

To make that showing, Plaintiffs are entitled to the agreements¹³ to determine whether they contain acceleration clauses, or other terms affecting the non-Handa Generics’ entry. Without the agreements, Plaintiffs will be deprived of relevant

¹³ Plaintiffs reserve the right to later seek production of related correspondence concerning the negotiation of the agreements.

evidence about whether the non-Handa Generics' licensed entry dates would be accelerated—*i.e.*, when those generics could have entered the market but-for the illegal payment. The denial also deprives Plaintiffs of evidence to rebut Defendants' arguments that the consent judgments, settlement agreements, or AZ's patent kept the non-Handa Generics out of the market, regardless of when Handa launched generic Seroquel XR.¹⁴ The number of non-Handa Generics that could launch earlier under the terms of their settlement agreements if Handa launched earlier will, in turn, affect the quantum of damages caused by Defendants' anticompetitive conduct, because as more generics enter the market, competition drives prices lower. Denying production would result in manifest injustice.

IV. CONCLUSION

For the foregoing reasons, the Court should reverse its decision, order AZ to produce its settlement agreements with the non-Handa Generics or, in the alternative, grant reargument.

¹⁴ If the Court affirms its prior decision, Plaintiffs reserve all rights to move to preclude Defendants from making any such arguments.

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